



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	<b>MAIL STOP AF</b>
Urs Jorimann et al.	)	Group Art Unit: <b>3685</b>
Application No.: 10/786,540	)	Examiner: CRISTINA O. SHERR
Filing Date: February 26, 2004	)	Confirmation No.: 3251
Title: METHOD OF CONTROLLING	)	
ELECTRONIC RECORDS	)	

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant requests review of the final rejection in the above-identified application.

This request is void of amendments and is filed concurrently with a Notice of Appeal.

The Examiner variously rejected under 35 U.S.C. §103 for alleged obviousness. For example, in numbered paragraph 8 on page 3 of the Office Action, claims 1, 18 and 20 are rejected under 35 U.S.C. §103(a) for alleged unpatentability over *Yaung et al* (U.S. Patent No. 6,446,069); in numbered paragraph 12, on page 5 of the Office Action, claim 2 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Yaung et al* (U.S. Patent No. 6,446,069) in view of "Title 21, CFR part 11 - Electronic Records; Electronic Signatures"; and in numbered paragraph 15 on page 5 of the Office Action, claims 4-17 and 19 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Yaung et al* (U.S. Patent No. 6,446,069). Applicants respectfully traverse this rejection.

Applicants' exemplary embodiments are directed to a method in which access rights to functions of an application software program for an analytical laboratory apparatus are assigned to various users based on a role-specific set of rights associated with various user roles. Electronic records are stored in a relational database that protects the records against

modification or deletion. A history of activities and access related to the software program and each electronic record is maintained through an audit trail. The electronic records can be authenticated by attaching at least one electronic signature of a user.

Claims 1 and 18 broadly encompass the foregoing features. For example, claim 1 recites a method for controlling electronic records comprising, among other steps, maintaining a history of access entries and activities performed in the application software program and authenticating each electronic record by attaching more than one electronic signature of users of a first group. Claim 18 recites a method comprising a signing procedure for authenticating electronic records with a plurality of electronic signatures, the method having among other steps, establishing a list of signature meanings to be attached to the electronic signatures, wherein each signature meaning in the list is ranked based on a signature level.

Regarding claim 1, the Examiner alleges that Applicants' maintaining feature is obvious based on the following rationale:

It is obvious that the purpose of a signature is to [know] who was there and what s/he did. Not to do so is the equivalent of signing a check with disappearing ink, and thus defeats the purpose of the signature. It is obvious, then, that signatures and the transactions they accompany are stored and that anything that is stored is logged and counted. *See Office Action*, pg. 2, numbered pgph 4.

Applicants disagree, as it appears the Examiner attempts to generalize Applicants' claim language for the convenience of formulating a rejection. In the context of Applicants' claims, an electronic signature of a user is a manner in which a user authenticates (i.e., approve) an electronic record. While not particularly relevant to Applicants' claims, even in the Examiner's example, a signing of a check amounts to an authentication or approval of the check by a user. In other words, Applicants' believe that the signing of a check is not reasonably related to the attaching of an electronic signature to an electronic record to sustain this rejection.

Turning to the *Yaung* patent, there is no teaching or suggestion of a manner of Applicants' claimed combination of maintaining a history of access entries and activities performed in an application software program; and authenticating an electronic record by attaching more than one electronic signature of users. Rather, the *Yaung* patent describes the capability to establish an access control system that checks application privileges to restrict user access when a user logs into an application program (e.g., col. 9, line 1 through col. 10, line 3; Figs. 4 and 5).

The Examiner alleges that under the Supreme Court's opinion in *KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007), a specific teaching is not required for a finding of obviousness. Applicants disagree. In *KSR*, the Court did not state that a specific teaching in a reference is not required, but rather held that "the obviousness analysis should not be confined by a formalistic conception of the words, teaching, suggestion, and motivation (TSM), or by overemphasizing the importance of published articles and the explicit content of issued patents." The Court added, "[t]here is no necessary inconsistency between the [TSM] test and the Graham analysis." In its analysis, the Court was most concerned with the narrow conception of the obviousness inquiry applied by the Federal Circuit through the TSM test, and not with the application of the TSM test in general.

In improperly applying the *KSR* decision, the Examiner attempts to incorporate features into the *Yaung* patent without providing any evidence or documentation to support its findings. Namely, the Examiner alleges that because using a signature, such as on a check, is well known, one of ordinary skill would have known to use of a signature in an access control system that checks application privileges to restrict user access when a user logs into an application program as disclosed in the *Yaung* patent. The Examiner makes this assertion, even when the *Yaung* patent fails to disclose or suggest the authentication of an electronic record as recited in Applicants' claims.

Even assuming *arguendo* that the Examiner's rejection was proper under KSR, which Applicants do not believe that it is, Applicants' respectfully submit that no reasonable nexus exists between the signing of a check and the system described in the *Yaung* patent to render Applicants' claims obvious. Because the Examiner has failed to provide any documentary evidence to support its finding of obviousness, the basis of the rejection is founded on Official Notice with an improper reliance on hindsight reasoning. Applicants timely challenged the Examiner's use of Official Notice in the last response while also requesting documentary proof of the asserted facts.

Regarding independent claim 18, the Examiner alleges that a user's association with an application privilege is the equivalent of a signature meaning attached to a signature. Applicants disagree.

As noted above, Applicants' claim 18 recites, in part, establishing a list of signature meanings to be attached to the electronic signatures, wherein each signature meaning in the list is ranked based on a signature level, and controlling said signing procedure so that the user can sign a record only with a signature meaning that ranks not lower than any previous signature attached to the record and not higher than the user's maximum signature level.

Contrary to the Examiner's assertions, the *Yaung* patent also fails to disclose or suggest the features recited in Applicants' claim 4. Particularly, the *Yaung* patent fails to disclose or suggest at least that the signature meaning indicates a signature status that an electronic record will have as a result of the electronic signature.

In the paragraph bridging pages 5 and 6 of the Office Action, the Examiner alleges that the *Yaung* patent discloses the aforementioned features. However, while the *Yaung* patent describes the capability to establish an access control system that checks application privileges to restrict user access when a user logs into an application program (e.g., col. 9, line 1 through col. 10, line 3; Figs. 4 and 5), this reference does not attach a signature

meaning as claimed. The Examiner cites various portions of the reference on which Applicants' claim feature reads. Yet none of these citations or any other portion of the *Yaung* patent disclose or suggest a feature in which a signature meaning indicates a signature status that an electronic record will have as a result of the electronic signature. At best, the *Yaung* patent discloses building a privilege vector that determines the restrictions for a user with respect to an application program (col. 6, lines 35-41).

The CFR document is applied to disclose requirements issued by the FDA as recited in Applicants' claim 2. Applicants respectfully submit, however, that this document fails to remedy the deficiencies of the *Yaung* patent with respect to Applicants' claimed signature meaning as discussed above.

In summary, the *Yaung* patent and CFR document when applied individually or collectively as relied upon by the Examiner, fail to disclose or suggest every feature recited in Applicants' claims. As a result, a *prima facie* case of obviousness has not been established.

### CONCLUSION

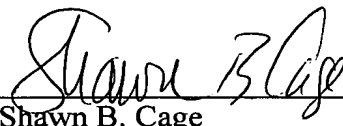
Based on the foregoing remarks, Applicants have identified errors in the final Office Action dated June 27, 2008. As a result, Applicants' request that the final rejection not be sustained.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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